REMARKS

Status of the Claims

Claims 1-2, 4-6, 8-32, 34-37, 43-44, 50-51, and 61-62 are pending. Claims 1-2, 4-6, 8-32, 34-37, 43-44, 50-51, and 61-62 are rejected. Claims 1, 8, 13, 20-21, 26, 28-31, 34, 43, and 50 are amended. Claims 3, 7, 33, 38-42, 45-49, 52-60, and 63-69 were canceled previously and claims 9-12 and 27 are canceled herein. Reconsideration of the pending claims is respectfully requested.

Amendments to the claims

Claims are amended or canceled to overcome rejections under 35 U.S.C. §112, first paragraph, 35 U.S.C. §102(b) and 35 U.S.C. §103(a), as discussed *infra*. Claim 1 is amended to incorporate the limitations of dependent claim 20 and recites a claim element of a means to deliver a pharmaceutical to a tissue during ablation thereof that is operably connected to the device. The preamble of claim 1 is amended to delete "to alter". Claim 1 is amended further to clarify claim language to recite that the abrasive member is adapted to contact an abrasive material delivered onto a tissue via a container operably connected to the device (pg. 25, ll. 5-6) or adapted to contact a tissue with an abrasive material attached thereon during ablation (pg. 18, ll. 19-21). Claim 8 is amended to recite a piezoelectric "actuator" instead of "material" (pg. 24, ll. 1-3) and to delete the phrase "an electro- or magneto-responsive material". Claims 9-12 are canceled. Claim 13 is amended depend from amended claim 1 and to clarify that the device further comprises a means to apply a driving force to the pharmaceutical that is operably connected to the device where the driving force is applied as identified in the claim (pg. 24, ll. 12-16). Claim 20 is amended to recite that the means to deliver the pharmaceutical is a container adapted to hold the pharmaceutical until delivery thereof (pg. 25, ll. 10-13). Claim 21 is amended to depend from amended claim 1. Claim 26 is amended to depend from amended claim 1 and incorporates the limitations of claim 27 to recite that the abrasive is a crystallized pharmaceutical or a powdered pharmaceutical (pg. 34, ll. 12-15). Claim 28 is amended to depend from amended claim 26. Claim 27 is canceled. Claim 29 is amended to depend from amended claim 1 and to clarify that the means to deliver a pharmaceutical is a reservoir adapted to contain the pharmaceutical

with a permeable membrane through which the pharmaceutical is controllably released. Claim 30 is amended to incorporate the limitation of "operably connected to said device" in claim 31 and to recite that the device further comprises a means to collect ablated tissue or a biomolecule from an ablation site (pg. 25, ll. 5-7). Claim 31 is amended to delete the phrase "operably connected to said device". Claims 34, 43 and 50 are amended to recited monitoring a change in a property of the tissue during ablation (pg. 25, ll. 17 to pg. 26, ll. 3). Claim 34 is amended to recite monitoring feedback about a change in an electric property (pg. 26, ll. 13 to pg. 28, ll. 21). Similarly, claims 43 and 50 are amended to recite monitoring a change in an optical property (pg. 29, ll. 1-9) or in a thermal property (pg. 30, ll. 6-13), respectively.

The 35 U.S.C. §112 First Paragraph Rejection

Claims 9-13 are rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. This rejection is respectfully traversed.

Claims 9-12 are canceled so the rejection is moot with respect to these claims.

For claim 13, the Examiner states that the specification does not enable a drive means that drives an abrasive member via piezoelectric material and with electrophoretic means. As discussed *supra*, claim 13 is amended to recite that the device of claim 1 further comprises an operably connected means to apply a driving force to a pharmaceutical which is applied via electrophoresis, etc. Thus, the means to drive the ablation member is distinct from the means to apply a driving force to the pharmaceutical. Accordingly, in view of the arguments presented herein, Applicants respectfully request that the rejection of claim 13 under 35 U.S.C. §112, first paragraph, be withdrawn.

The 35 U.S.C. §102 Rejections

Claims 1-2, 4-6, 8, 14, 18-26, and 62 are rejected under 35 U.S.C. §102(b) as being anticipated by **Suroff** (U.S. Patent No. 5,150,492). Claims 1-2, 4-6, 8, 13-18, 20-26, and 62 are rejected under 35 U.S.C. §102(b) as being anticipated by **Bernaz** (WO 02/053046; U.S. Pub. No. 20040092959 relied on for corresponding English translation and citation). These rejections are respectfully traversed.

The Examiner states that **Suroff** discloses a device for altering tissue comprising an abrasive member contacting abrasive material on tissue or thereon and means to drive the member at high frequency. The device is capable of use with various tissues and various lubricants, i.e. water, and pharmaceuticals. In addition, the Examiner states that **Bernaz** discloses a device for altering or ablating tissue comprising an abrasive member contacting abrasive material on tissue or thereon, electro or magneto responsive material (motor) means to drive the abrasive member at high frequency, abrasive material of aluminum oxide 50-90 microns, lubricant comprising water and electrophoretic driving means (PPs 0019, 0025, 0031-0032, 0046-0047, 0052, 0055, and 0062-0063).

Suroff teaches an ultrasonic toothbrush with a removable head mounted to an ultrasonic power means (Abstract). The ultrasonic toothbrush is configured to clean tooth and gingival surfaces via ultrasonic energy to remove stains, plaque and tartar without damages to these surfaces (col. 1, ll. 29-33; col. 7, ll. 12-58). **Suroff** does not teach a device effective to ablate tissue. **Suroff** also does not teach a means to deliver a pharmaceutical that is operably connected to the ultrasonic toothbrush. At best **Suroff** discloses that water or a dentifrice may be taken into the mouth prior to beginning the brushing procedure (col. 9, ll. 68 to col. 10, ll. 2).

Bernaz teaches a device for cosmetic skin dermabrasion that has a curved abrasive surface, held by a support mounted in a housing, which is driven to oscillate about its axis to effect the abrasion of the epidermis (Abstract; PP 0016). As with **Suroff, Bernaz** does not teach a means to deliver a pharmaceutical that is operably connected to the dermabrasion device and is adapted to deliver the pharmaceutical during ablation. At best **Bernaz** teaches that after dermabrasion a gel or other treating product may be applied to the treated epidermis and caused to penetrate through the skin via the application of a high magnetic flux of energy or via laser produced radiation (pg. 4, PP 0032, 0063).

Applicant's claimed invention recites a device that comprises, *inter alia*, a means to deliver a pharmaceutical to a tissue during ablation thereof that is operably connected to the device. Furthermore, claims 2, 4-6, 8, 13-26, and 62 depend directly or indirectly from amended independent claim 1 and further limit the tissue (claims 4-6), the means to drive the abrasive member (claim 8), the abrasive (claims 14-19, 26), the

pharmaceutical (claims 14-25), the means to deliver the pharmaceutical (claim 20), and the lubricant (claim 62) or further limits the device by including a housing means (claim 2) or a means to apply a driving force to the pharmaceutical during ablation (claim 13). As claim 1 is amended to incorporate a claim element novel over **Suroff** and **Bernaz**, then the incorporation of any of these dependent claims into claim 1 cannot be anticipated by **Suroff** or **Bernaz**. At a minimum, absent teachings of a device comprising an operably connected means to deliver a pharmaceutical to the tissue during ablation as recited in Applicants' amended claim 1, neither **Suroff** nor **Bernaz** can anticipate amended claim 1. Accordingly, Applicants respectfully request that the rejections of claims 1-2, 4-6, 8, 13-26, and 62 under 35 U.S.C. §102(b) be withdrawn.

The 35 U.S.C. §103(a) Rejections

Claims 27-28, 34-37 and 50-51 are rejected under 35 U.S.C. §103(a) as being unpatentable over **Bernaz** *et al.* as applied to claims 1 and 26 above, and further in view of **Eggers** *et al.* (U.S. Patent No. 6,066,134). This rejection is respectfully traversed.

The Examiner states that **Bernaz** discloses the claimed invention except for monitoring feedback using an electrical property of the tissue with the device, crystallized pharmaceutical, and monitoring feedback about a thermal property of the tissue. The Examiner also states that **Eggers** teaches monitoring feedback using a heartbeat and a thermal property of the tissue to perform a safe ablation procedure. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of **Eggers** in the device of **Bernaz** to increase the safety of the ablation procedure for better patient outcome.

Bernaz is as stated by Applicants' *supra*. **Eggers** *et al.* teach an electrosurgical probe comprising a shaft having an electrode array, as active electrode, at its distal end, a return electrode recessed within the shaft and a connector at its proximal end for coupling the electrode array to a high frequency power supply (Abstract). **Eggers** *et al.* teach monitoring the temperature of the surface of the electrode array to regulate current flow if the temperature exceeds selected limits (Col. 14, ll. 44-63). **Eggers** *et al.* teach monitoring the heartbeat so that the high frequency voltage is pulsed to cut or ablate heart tissue to form

a revascularization channel during systole of the heart and a thermal property of the tissue to perform safe ablation of heart tissue during a revascularization procedure (col. 23, ll. 43-56).

Applicants have canceled claim 27. Applicants invention as recited in amended claim 1 is discussed *supra*. **Bernaz** neither teaches nor suggests the claim element of an ablative device including an operably connected means to deliver a pharmaceutical to a tissue during ablation thereof. **Bernaz** specifically teaches that any treating compound is applied to the treated epidermis after treatment and requires the application of electromagnetic radiation to cause permeation of the compound. Combining **Eggers** *et al.* with **Bernaz** does not remedy this deficiency. Therefore, amended claim 1 is non-obvious over **Weaver** *et al.* in view of **Eggers** *et al.*

Dependent claims 34 and 50 have been amended to recite that the control means monitors feedback about a change in an electrical property or thermal property of said tissue with depth of ablation, respectively, as discussed *supra*. The magnitude of the electrical signal generated by a heartbeat increases with depth of ablation (pg. 28, ll. 15-21). **Eggers** *et al.* are not monitoring these changes but only synchronizing heartbeat with the application of the pulsed voltage. This does not correlate with depth of ablation. Similarly, **Eggers** *et al.* do not monitor a change in thermal properties of tissue during ablation to regulate depth of ablation as in Applicants' invention, but rather monitor the temperature of the electrode array. When the stratum corneum of skin is completely removed an abrupt and significant change in infrared emissions from the skin occurs and ablation is stopped (pg. 30, ll. 6-13). As the effleuraging action of the abrasive surface of the device in **Bernaz** is continuous, gentle (pg. 1, PP. 0001) and does not require the application of high frequency voltage, one of ordinary skill in the art would find no motivation to even combine **Eggers** *et al.* with **Bernaz**. Furthermore, as do claims 34 and 50, claims 28, 35-37 and 51 depend directly or indirectly from amended claim 1 and further limit the crystalline pharmaceutical, and the means to monitor a change in an electrical property or a thermal property, respectively. If amended claim 1 is not rendered obvious by the combination of **Bernaz** with **Eggers** *et al.*, then neither are claims 28, 34-37 and 50-51 rendered obvious by the combination. Accordingly, in view of the amendments and arguments presented herein,

Applicants respectfully request that the rejection of claims 28, 34-37 and 50-51 under 35 U.S.C. §103(a) be withdrawn.

Claim 29 is rejected under 35 U.S.C. §103(a) as being unpatentable over **Bernaz** *et al.* as applied to claim 20 above, and further in view of **Unger** (U.S. Patent No. 6,416,740). This rejection is respectfully traversed.

The Examiner states that **Bernaz** discloses the claimed invention except for a reservoir with a permeable membrane to release a pharmaceutical to the tissue. **Unger** teaches the use of a permeable membrane to release the pharmaceutical in a patch applied to the skin of a patient (Col. 69, ll. 11-14). The Examiner states that it would have been obvious to one of ordinary skill in the art to use the patch in **Unger** in the device of **Bernaz** in order to provide a convenient patch for drug delivery through the skin after ablation.

Unger teaches an acoustically active targeted therapeutic delivery system where ultrasound enhances delivery of the therapeutic (Abstract). The therapeutic, e.g., steroid prodrugs, together with a penetration enhancer may be administered transdermally in a patch or reservoir with a permeable membrane in a patch applied to the skin of a patient (col. 69, ll. 11-14).

Applicants' invention with respect to amended claims 1 and 29 are discussed *supra*. No teaching or suggestion is found in **Bernaz** or **Unger** to operably incorporate a reservoir into the device. This combination does not remedy the deficiency in **Bernaz** as discussed *supra*. As amended, claim 29 limits the delivery means operably connected to the device to a reservoir having a permeable membrane that controllably releases the pharmaceutical during ablation.

Even should one of ordinary skill in the art may find motivation to use a transdermal patch having a reservoir with a permeable membrane, as taught in **Unger**, with the dermabrasion device taught in **Bernaz**, this is not Applicants' invention recited in amended claim 1. **Bernaz** teaches application of a treating compound with electromagnetic radiation for permeation thereof after abrasion. At a minimum, one of ordinary skill in the art would recognize that application of a transdermal patch over the site of abrasion would interfer, if not render inoperable, the device of **Bernaz** which requires oscillating an abrasive

surface against the epidermis at the site. One of ordinary skill would more likely be motivated to incorporate the permeable reservoir taught in **Unger** with the means to deliver the electromagnetic radiation as a way of applying and causing permeation of a treating compound to the treated epidermis. Thus, the combination of **Bernaz** with **Unger** does not render amended claim 1, and by extension, amended dependent claim 29, obvious. Accordingly, in view of the amendments and arguments presented herein, Applicants respectfully request that the rejection of claim 29 under 35 U.S.C. §103(a) be withdrawn.

Claims 19 and 61-62 are rejected under 35 U.S.C. §103(a) as being unpatentable over **Bernaz** *et al.* as applied to claim 1 above, and further in view of **Melbouci** *et al.* (U.S. Patent No. 6,562,090). This rejection is respectfully traversed.

The Examiner states that **Bernaz** discloses the claimed invention except for using a lubricant of water and glycerol with the abrasive. The Examiner states that **Melbouci** *et al.* teach using water and glycerol with a lubricant to provide a stabilized suspension of abrasive in lubricant (claim 1). It would have been obvious to one of ordinary skill in the art to use a water and glycerol lubricant in the device of **Bernaz** to facilitate the use of the abrasive.

Claims 19 and 61-62 limit the abrasive as comprising a lubricant. **Melbouci** *et al.* disclose a fluid abrasive for dentifrice systems, i.e., toothpastes, that may comprise the abrasive, a water-swellable or water-soluble polymer and water mixed with glycerol (col. 3, ll. 10-44). Neither **Bernaz** nor **Melbouci** *et al.* teach that the lubricant is electrically conductive as recited in amended claim 62.

Combining **Melbouci** *et al.* with **Bernaz** does not remedy the deficiency in **Bernaz** as to amended claim 1, as discussed *supra*, because neither reference teaches nor suggests operably incorporating a means to deliver a pharmaceutical during ablation in an ablative device. The use of any lubricant with the device of **Bernaz** does not render amended claim 1 obvious. Thus, if the combination of **Bernaz** and **Melbouci** *et al.* do not render amended claim 1 obvious, then neither are claims 19 and 61-62, which depend directly or indirectly from amended claim 1, then neither are claims 19 and 61-62 rendered obvious.

Accordingly, in view of the amendments and arguments presented herein, Applicants request that the rejection of claim 19 and 61-62 under 35 U.S.C. §103(a) be withdrawn.

Claims 43-44 are rejected under 35 U.S.C. §103(a) as being unpatentable over **Bernaz** *et al.* as applied to claim 1 above, and further in view of **Weaver** *et al.* (U.S. Pub. No. 2002/0065533). This rejection is respectfully traversed.

The Examiner states that **Bernaz** discloses the claimed invention except for a control means to monitor fluorescence or reflectance of the tissue comprising radiant source, detector, and controller. **Weaver** teaches the use of control means to monitor tissue fluorescence or reflectance to facilitate ablation (PP. 19, 34, 47, 58-59, 104-112, 115, and 128). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of **Weaver** in the invention of **Bernaz** in order to safely ablate tissue.

Weaver *et al.* disclose an apparatus used for creating microconduits by impingement on the skin of accelerated microparticles having enough velocity to scission the skin for localized molecular and ionic transport to/from tissue through the microconduits (Abstract; PP. 0016). A molecule may be delivered through the microconduits after their formation by application of the molecule to one or more of the microconduits, such as by storing the molecule in at least one puncturable capsule in proximity to at least one microconduit (PP. 0019) or by sealing a column containing the molecule to the tissue around a microconduit, e.g., using a pipette with a rubber bulb attached (PP. 0132). The presence of blood in the microconduit may be detected before the blood entering the microconduit moves out of the microconduit and leaves the tissue by comparing the ratio of reflected red light to reflected blue light (PP. 0108-0109).

Claims 43-44, as amended, limit the device by incorporating a means to monitor feedback about a change in an optical property, such as fluorescence or reflectance. Combining **Weaver** *et al.* with **Bernaz** does not remedy the deficiency in **Bernaz** as to amended claim 1, as discussed *supra*, because neither reference teaches nor suggests operably incorporating into an ablative device a means to deliver a pharmaceutical during ablation. At best **Weaver** *et al.* teach methods of delivering a pharmaceutical to a microconduit after its

formation. Even should one of ordinary skill in the art be motivated to use the delivery methods in **Weaver** *et al.* to apply a treating compound to the treated epidermis, this is still not Applicants' invention recited in amended claim 1. The combination of **Bernaz** with **Weaver** *et al.* does not render amended claim 1 obvious.

Furthermore, one of ordinary skill in the would not be motivated to use reflectance, as taught in **Weaver** *et al.*, as a monitoring means for the dermabrasion device of **Bernaz**. **Weaver** *et al.* teach using reflectance to determine that a microconduit has first reached the capillary bed by the change in reflectance due to the initial appearance of blood. This allows for safe blood collection or to measure an analyte in the blood within the microconduit (PP. 0109, 0137). **Bernaz** teaches that the dermabrasion device is configured to not completely remove the epidermis (PP. 0017-0018) and as the epidermis contains no blood vessels, reflectance monitoring as taught in **Weaver** *et al.* would not be applicable. Thus, since the combination of **Bernaz** with **Weaver** *et al.* does not render Applicants' claim 1 obvious then neither can dependent claims 43-44 be obvious in view of the combination. Accordingly, in view of the amendments and arguments presented herein, Applicants respectfully request that the rejection of claims 43-44 under 35 U.S.C. §103(a) be withdrawn.

This is intended to be a complete response to the Final Office Action mailed March 9, 2005. Applicant submits that the pending claims are in condition for allowance. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

Date: June 13, 2005

ADLER & ASSOCIATES
8011 Candle Lane
Houston, Texas 77071
Tel: (713) 270-5391
Fax: (713) 270-5361
badler1@houston.rr.com

Benjamin Aaron Adler, Ph.D., J.D.
Registration No. 35,423
Counsel for Applicant